OCT 2 2 2001

PART B: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K012625

Submitter:

Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Contact:

Don Selvey
Vice President, Regulatory Affairs and Quality Assurance
(480) 763-5300

Date of preparation:

August 10, 2001

Name of device:

Trade/Proprietary Name:
Reprocessed Unipolar Laparoscopic/Endoscopic Instruments

Common or Usual Name:
Unipolar Laparoscopic/Endoscopic Instruments

Classification Name: **Endoscope and Accessories** and/or **Electrosurgical Cutting and Coagulation Device and Accessories**

Reprocessed devices:

Manufacturer	Description	Model
Ethicon	Endopath ® Endo Metzenbaum Scissor	BMS10
Ethicon	Endopath ® Curved Scissor	DCS12
Ethicon	Endopath ® Hook Scissor	DHS14
Ethicon	Endopath ® Micro-Scissor	DMS15
Ethicon	Endopath ® Curved Scissor	5DCS
Ethicon	Endopath ® Curved Scissor, Short	SCS12
Ethicon	Endopath ® Straight Grasper	DSG22
Ethicon	Endopath ® Modified Allis Grasper	DSG23
Ethicon	Endopath ® Ratchet Grasper	5DSG
Ethicon	Endopath ® Claw Extractor	DEX41
Ethicon	Endopath ® Curved Dissector	DCD32
Ethicon	Endopath ® Straight Dissector	DSD33
Ethicon	Endopath ® Curved Dissector	5DCD
Ethicon	Endopath ® Curved Dissector	SCD32

Predicate device(s):

K#	Device Description	Procode
K984240	Ethicon Endopath ® Endoscopic Instrument	GEI
K934784	Ethicon Endopath ® Endoscopic Electrosurgical Forceps	GEI
K930933	Ethicon Endopath ® Endoscopic Surgical Instruments	GCJ

Device description:

Unipolar laparoscopic/endoscopic instruments are electrosurgical instruments consisting of a rigid plastic handpiece with loop handles connected to the distal end effector jaw by an elongated, narrow-diameter insulated barrel or shaft. The devices are designed to be inserted through an appropriately sized trocar sleeve or cannula. The jaws are operated by the handpiece loop handles and may be shaped as scissors, dissectors or graspers. The jaws of some models may be rotated by manipulating controls on the handpiece.

The blades or jaws of unipolar laparoscopic/endoscopic instruments can deliver a cauterizing current that enters the instrument through the unipolar cautery connector on the handpiece, runs down the insulated shaft and through the tissue in the blades or jaws.

Intended use:

Reprocessed unipolar laparoscopic/endoscopic instruments, including scissors, dissectors, and graspers are intended for use in minimally invasive surgical procedures.

Indications statement:

Reprocessed unipolar laparoscopic/endoscopic instruments, including scissors, dissectors, and graspers, are to be used for patients requiring minimally invasive surgical procedures to manipulate and manage internal soft tissue by grasping, cutting, dissecting, cauterizing, or coagulating tissue.

Technological characteristics:

The intended use and technological features of the reprocessed devices do not differ from the legally marketed predicate device(s). Both the reprocessed device(s) and the predicate device(s) have the same materials and product design. The technological characteristics of the reprocessed unipolar laparoscopic/endoscopic scissors, dissectors, and graspers are the same as those of the legally marketed predicate devices.

Alliance Medical Corporation's reprocessing of unipolar laparoscopic/endoscopic instruments includes removal of adherent visible soil and decontamination. All unipolar laparoscopic/endoscopic instruments are tested for electrical continuity. Unipolar laparoscopic/endoscopic **scissors** are tested for cutting function. **Graspers** and **dissectors** are tested for the ability of the jaws to grasp appropriately.

Performance data:

Performance data demonstrates that Reprocessed Unipolar Laparoscopic/Endoscopic Instruments perform as originally intended.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Alliance Medical Corporation concludes that the modified device (Reprocessed Unipolar Laparoscopic/Endoscopic Instruments) is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2001

Mr. Don Selvey
Vice President, Regulatory Affairs
and Quality Assurance
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Re: K012625
Trade/Device Name: Reprocessed Unipolar Laparoscopic/Endoscopic Instruments
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 10, 2001
Received: August 13, 2001

Dear Mr. Selvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Indications for Use Statement

510(k) Number (if known): K012625

Device Name: Alliance Medical Corporation Reprocessed Unipolar Laparoscopic/Endoscopic Instruments

Indications for Use: Reprocessed Unipolar Laparoscopic/Endoscopic Instruments, including scissors, dissectors, and graspers, are to be used for patients requiring minimally invasive surgical procedures to manipulate and manage internal soft tissue by grasping, cutting, dissecting, cauterizing, or coagulating tissue.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use ✓ or Over-the-Counter Use
(per 21 CFR 801.109)

510(k) Number K012625